significance difference in the efficacy and safety in nucleos(t) ide-naïve CHB patients with HBV DNA greater than 6 log10 in the medical center.

PGI2
EFFECTIVENESS OF PROBIOTICS IN IRRITABLE BOWEL SYNDROME: A SYSTEMATIC REVIEW WITH META-ANALYSIS
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OBJECTIVES: To investigate the efficacy of probiotics in irritable bowel syndrome (IBS) patients, this meta-analysis was performed. **METHODS:** The collected data contained twenty-four clinical trials which fifteen were eligible for meta-analysis and nine were reviewed systematically. All studies were randomized placebo-controlled trials in patients with IBS that investigated the efficacy of probiotics in IBS improvement. Trials were evaluated with Relative Risk (RR) with 95% confidence interval (95% CI). Cochran Q test was used to test heterogeneity with P value 0.05 (P<0.05). Egger and Begg-Mazumdar tests in funnel plot were calculated as publication bias indicators. **RESULTS:** Probiotics reduced pain severity, symptom severity score and induced adequate general symptom improvement. Distension, bloating, and flatulence were not improved after probiotics treatment when compared to placebo. **CONCLUSIONS:** Collectively, the results demonstrated the beneficial efficacy of probiotics compared with placebo in IBS patients.

PGI3
ESTABLISHMENT OF A HEPATITIS C VIRUS (HCV) COHORT IN A LARGE ISRAELI HMO
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OBJECTIVES: Hepatitis C virus (HCV) affects an estimated 130 million people worldwide and is a major cause of chronic liver disease. Real-world data is needed to better understand the epidemiology of HCV and its complications, as well as treatment patterns and outcomes. The objective of this study is to establish a cohort of HCV carriers in a large health maintenance organization, with comprehensive data on treatment and disease outcomes. **METHODS:** The HCV cohort will use data available since 1998 from the computerized databases of Maccabi Healthcare Services, the second largest HMO in Israel, with approximately 2 million members. HCV cases are included based on diagnostic codes (ICD9-CM), laboratory data (e. g. detection of HCV antibodies and RNA) and dispensed prescriptions for HCV treatment. The cohort includes demographic data (age, sex, immigration and socioeconomic status), clinical data (e. g. BMI; comorbidities), treatment patterns, virological outcomes, and HCV complications – including cirrhosis, hepatocellular carcinoma, liver transplants, and mortality. **RESULTS:** At the end of 2012, HCV infection was identified among 10,648 patients, corresponding to an age-adjusted prevalence rate of 5 per thousand. The highest prevalence was found among males and in the age group 35-55 yrs. Two thirds of HCV patients were immigrants from Eastern Europe. HCV genotype 1 was predominant (67%). Over a third of patients had at least one recorded purchase of interferon, and treated patients were less likely to have chronic diseases such as diabetes or cardiovascular disease, compared to untreated patients. **CONCLUSIONS:** The establishment of a HCV cohort in MHS can serve as a basis for retrospective database studies and can be periodically updated to follow up existing patients and identify incident HCV cases. For example, future studies can examine the adherence and efficacy of treatments, and associations between HCV and chronic diseases such as chronic kidney disease.

PGI4
THE INCIDENCE OF UPPER AND LOWER GASTROINTESTINAL COMPLICATIONS: A RETROSPECTIVE STUDY USING A JAPANESE HEALTH CARE DATABASE
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OBJECTIVES: The objective of this study was to investigate the incidence of complications (bleeding and perforation) with hospitalization from both upper and lower GI tract in Japanese population using a health care claims database (HDB). **METHODS:** All of the claims data of the patients who have a history of hospitalization due to complications from GI tracts between January 2011 and December 2012 were extracted from the HDB which holds about 1.8 million peoples' claims data under employment-based health insurance. In order to identify upper and lower GI events precisely, we confirmed them when a diagnosis of a GI event in the claims (ICD-10 code) was accompanied by a record of examination and/or endoscopic or surgical treatment relevant to upper and lower GI complications. **RESULTS:** The total number of person-years at risk was 1.2 million person-years in 2012. The incidence rates in upper and lower GI events were 48 and 41 per 100,000 person-years, respectively. Twenty-one percent of the lower events originated in bleeding from hemorrhoid or related treatments (eg. hemorrhoidectomy). Age-group analyses in the upper vs. lower events, except those from hemorrhoid, were 27 vs. 17, 57 vs. 46 and 184 vs. 104 per 100,000 person-years in 20-39, 40-59, and 60+ years groups, respectively. Data from 2011 were consistent with these observations on the ratio of upper to lower GI events and the age-based incidence, indicating the robustness of the results. **CONCLUSIONS:** This was the first study to investigate the incidence from both upper and lower GI complications with hospitalization in a real clinical setting in Japan using a single large data source. We confirmed that a number of GI events occurred in both upper and lower GI tract and the incidence rates of both events were increased with age in a real world setting.

PGI5
ASSOCIATIONS BETWEEN CROHN'S DISEASE SEVERITY AND SPECIFIC SOCIO-DEMOGRAPHIC, QUALITY-OF-LIFE AND COPING FACTORS
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OBJECTIVES: To study possible associations and assess the impact of socio-demographic, quality-of-life and coping factors on the severity of Crohn's disease patients in Israel. **METHODS:** Consecutive Crohn's disease patients undergoing clinical follow-up at the Inflammatory Bowel Diseases Clinic completed the following questionnaires: SF-36 quality-of-life, Ways of Coping, and socio-demographic details. Crohn's disease severity was measured by Harvey-Bradshaw Index (HBI) expanded to include pharmaceutical and surgical therapies as well as medical and surgical hospitalization information. Based on these data, a multifactorial model was built using multivariate linear regression. **RESULTS:** There were altogether 192 patients: 81 (42.2%) men (age 36.8 ± 14.5 years, disease duration 11.4 ± 8.6 years, education 13.7 ± 2.7 years, HBI 7.6 ± 4.9) and 111 (57.8%) women (age 41.4 ± 15.6*, duration 14.0 ± 9.3*, education 14.2 ± 2.8, HBI 8.4 ± 4.8; *p < 0.05 vs. men). The multifactorial model showed the following significant predictors of disease severity: age (beta = –0.250, p = 0.006), number of children (beta = 0.245, p = 0.008), SF-36 General Health score (beta = –0.378, p < 0.01), coping/sense of humor (beta = 0.209, p = 0.011), and coping/acceptance (beta = –0.183, p = 0.024). The model accounted for 29% of explained variance, with Adjusted R^2 = 0.26. Gender, education and socio-economic status were not predictors of disease severity. **CONCLUSIONS:** All of the indicated factors (age, family size, coping skills) had a significant effect on the severity of Crohn's disease. In addition to prescribing medications, physicians should pay special attention to these factors as part of an overall management plan for their Crohn's disease patients.

PGI6
DEVELOPMENT AND EXTERNAL VALIDATION OF A RISK CALCULATOR FOR PREDICTING ANEMIA IN PATIENTS TREATED WITH TRIPLE THERAPY (TT) CONTAINING BOCEPREVIR (BOC), PEGYLATED INTERFERON AND RIBAVIRIN (PR)
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OBJECTIVES: To develop and validate a risk calculator for the prediction of anemia occurring after 8 weeks of TT using BOC+PR among Hepatitis C Virus (HCV) genotype 1 patients based on risk factors. **METHODS:** Data for all randomized HCV genotype 1 patients starting therapy with BOC+PR and who received at least one dose of BOC in three phase 3 clinical trials (PN05101, PN5216 and PN5514) were included. The outcome of interest was the prediction of anemia, defined as hemoglobin <10 g/L after 12 weeks of TT with BOC+PR (this included 4 weeks of lead-in treatment using PR). Logistic regression was used to develop the risk calculator model by analyzing the association of each variable with the likelihood of developing anemia while on treatment. Baseline variables were included as covariates in the model. Linearity assumptions were relaxed with the use of restricted cubic splines. Bootstrapping, with 1000 resamples, were used in conjunction with estimation of discrimination and calibration. **RESULTS:** Following a stepdown procedure that eliminated predictors that did not contribute to the overall model concordance index, nine variables remained in the final model: age, hemoglobin, gender, cirrhosis, hematologic counts, Alkaline phosphatases levels, and creatinine. This model had a boostrap corrected concordance index of 0.775. The model was cross-validated by sequentially omitting each of the three randomized trials from the model development and using the omitted trial as a test set; the concordance indices following this procedure ranged from 0.75 to 0.85. Calibration of the model, assessed graphically, indicated reasonably close agreement between predicted and observed proportions. Calibration held following trial cross validation as well. **CONCLUSIONS:** The model calibrated well and demonstrated good predictive ability. This tool may be useful for identifying and subsequently managing HCV patients at relatively high risk for developing anemia if treated with BOC+PR.

GASTROINTESTINAL DISORDERS – Cost Studies

PGI7
BUDGET IMPACT ANALYSIS OF SOFOSBUVIR FOR THE TREATMENT OF HEPATITIS C IN THE VENETO REGION, ITALY
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OBJECTIVES: Hepatitis C virus (HCV) infection is one of the main causes of chronic liver disease worldwide. Sofosbuvir, a nucleotide analogue inhibitor of HCV RNA-dependent RNA polymerase, has been approved in Europe for the treatment of chronic hepatitis C genotypes 1-6. This study aims to estimate the budget impact of sofosbuvir in patients who live in the Veneto Region. **METHODS:** Population data were obtained from a regional survey. The survey was conducted by the Department of Molecular Medicine of Padua University in order to identify the number of patients with advanced stage disease or more rapid disease progression. At the time of this study, the Italian price of sofosbuvir has not been defined so it was estimated that a full 12 week course of sofosbuvir would cost as Swedish price: 42.653 € (85.306€ for a 24 week treatment). Total costs include costs for other drugs which might be used in combination. **RESULTS:** In Veneto Region, there are 835 patients with severe Hepatitis C genotype 1 (n=493); genotype 2 (n=94), genotype 3 (n=178), genotype 4 (n=70) and about 40% of them need a 24 week treatment. Moreover, there are 100 patients awaiting liver transplantation and 70 patients with post-transplant recurrence of HCV infection. Therefore, the total estimated expenditure would be about €66.000.000 for all the 1005 patients and about €34.000.000 for the 455 patients (45%) with very high priority to treatment. **CONCLUSIONS:** High prices for new drugs are a growing concern to payers, given the large number of innovative drugs in development and the limited health care resources. Due to high costs, economic analyses are needed to estimate the budgetary impact for the Regional Health System (RHS) with sofosbuvir.